

Remarks/Arguments:

I. Status

The Office Action dated October 24, 2005 (the "Office Action") has been carefully reviewed. Claims 1, 13 and 16-18 have been amended and claims 19-20 have been added. Accordingly, claims 1-20 are pending in this application. Reconsideration of this application, as amended, is respectfully requested.

II. Specification

In the Office Action, the specification was objected to for omitting a description of the drawings. The Applicants have submitted a brief description of the drawings and other amendments to the specification. The Applicants believe that the corrections set forth above correct the errors identified by the Examiner and other errors found during the Applicants' review. Accordingly, the Applicants respectfully submit that the objection to the specification has been overcome.

III. The Rejection of Claims under 35 USC §112

In the Office Action, claims 13-18 were rejected under 35 U.S.C. 112 for claiming a surface feature on a "head." The Examiner further requested an identification of the discussion in the specification of a screw and bore as recited in claims 12 and 17.

Claims 13 and 16-18 have been amended to more clearly identify the invention as directed to a feature on a body. With respect to the screw elements recited in claims 11 and 17 and the bore recited in claim 17, the Examiner's attention is respectfully directed

to the specification at FIG. 9 and the specification at page 7, last paragraph, disclosing the use of bone screws 52 to attach the scaffold 45 to the underlying bone. Continuing with the foregoing paragraph at page 8 of the specification, the Applicants have disclosed that in an alternative embodiment, the screws are sized to extend completely through the bone and into a bore (not shown) in the mounting platform.

Accordingly, the Applicants respectfully submit that the Examiner's rejections have been overcome and the elements recited in the claims are fully supported by the specification.

IV. The Rejection of Claims under 35 USC §102

In the Office Action, claims 1, 4-5, 8-10, 13-14 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,939,498 to Lee et al. (hereinafter "Lee"). Claims 11-15 were further rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,008,431 to Caldarise et al. (hereinafter "Caldarise"). The Applicants respectfully submit that these claims are allowable in view of the foregoing amendments and the following remarks.

The Present Invention

The present invention relates to a soft tissue attachment system and method. In one exemplary method, a partial hip replacement includes the removal of the head and neck of a femur. The soft tissue attached to the trochanter that extends from the neck, however, is not removed. Rather, the trochanter is separated from the neck portion of the femur either before or after the neck has been resected. One surface of the trochanter is

then formed into a feature that allows the trochanter to be mechanically interlocked with a complementary feature on a prosthesis. For example, a keystone slot with dovetailed undercuts may be formed in the bone tissue of the trochanter.

Therefore, in accordance with principles of the present invention, a mechanical interlock is formed along the prosthesis/bone tissue interface.

Lee

Lee is directed to an endoprosthetic femoral head device modified to facilitate implantation involving detachment and re-attachment of the greater trochanter. (Lee at Abstract). To this end, Lee discloses the use of a prosthesis 10 with a slot 14 formed therein. (Lee at column 2, lines 11-17 and FIG. 1). An elongate member 20 includes a shaft 21 with an enlarged end portion 22 which is slidably received in the slot 14. (Lee at column 2, lines 21-25 and FIG. 1). When the end portion 22 is positioned within the slot 14, the shaft 21 is inserted through a bore 54 which extends from the resected surface of the trochanter to the side opposite the resected surface. (Lee at column 2, lines 45-51 and FIG. 1). A washer 50 and a fastener 40 are then placed over the portion of the shaft 21 which extends out of the trochanter to compress the trochanter to the prosthesis 10. (Lee at column 2, lines 50-52 and FIG. 1). Finally, a bolt 60 is threaded into the slot 14 to maintain the enlarged head 22 of the member 20 within the slot 14. (Lee at column 2, lines 58-61 and FIG. 1).

Lee thus discloses mechanically fastening a trochanter to a prosthesis using a first bolt which extends completely through the trochanter and into the prosthesis and a second bolt which keeps the first bolt engaged with the prosthesis.

Caldarise

Caldarise discloses a prosthesis that allows for bone ingrowth. (Abstract). In the device of Caldarise, roughened regions 28 are formed on the lower stem surface 26 of an implant. (Caldarise at column 3, line 67 through column 4, line 3). The roughened regions 38 include recesses 30. (Caldarise at column 4, lines 19-21). When implanted, lower portion 26 of the stem is wedged into the portion of a femur remaining in a patient after the ball and trochanter have been resected. (Caldarise at column 3, lines 60-67).

Accordingly, the recesses of Caldarise are wedged into a patient's femur and are therefore used with non-resected bone portions which have not been formed into a complementary feature. Thus, as shown in FIG. 2, there is a gap existent between the floor (f) of the recesses and the adjacent bone 50. Because the remaining portion of the femur is not shaped complementary to the recess, this gap is limited to "below three millimeters" so as to allow bone from the "inner wall of the femur 50" to grow into the recess. (Caldarise at column 4, lines 46-54).

Thus, Caldarise discloses the use of recesses on a stem that is implanted within a non-resected portion of a femur, wherein the recesses are not configured complementary to a surface feature of the femur.

Discussion Regarding Patentability of Claim 1

1. Claim 1

Claim 1, as amended recites:

A method for repair of a joint comprising the steps of:
removing a portion of a bone having natural soft tissue attached thereto;

implanting an implant within the remaining bone leaving an exposed surface of the implant;

preparing a surface of the removed portion of bone to provide the surface with a surface feature to mechanically interlock with a complementary feature defined on the exposed surface of the implant; and

mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant when the implant is within the remaining bone while the natural soft tissue is still attached to the removed portion of bone such that the complementary feature of the implant does not extend completely through the removed portion of bone.

Thus, claim 1 recites a method wherein a surface of the removed bone portion is shaped into a feature which interlocks with a feature on the prosthesis resulting in a bone tissue-prosthesis interlock along the bone/prosthesis interface wherein the surface feature of the implant does not extend completely through the removed bone.

1. Lee Does Not Disclose a Bone Tissue-Prosthesis Interlock

The Examiner rejected claim 1 based upon the proposition that Lee discloses the steps of claim 1. (Office Action at page 4). The Applicants have amended claim 1 to more clearly distinguish the claimed invention.

Specifically, the Examiner has alleged that the recited interlock is disclosed by the bore 54 and member 20 of Lee. The member 20 is a bolt with an enlarged head. The bolt extends completely through the trochanter. Moreover, the bolt with an enlarged head is not a "surface feature" of a prosthesis. Rather, the bolt interacts with a surface feature of the prosthesis, namely, the slot in the prosthesis that is open to the exposed surface of the prosthesis. The slot, however, does not interlock with the trochanter.

Therefore, Lee does not disclose the engagement of a surface feature of a prosthesis with a surface feature of a trochanter without the surface feature of the prosthesis extending completely through the trochanter. Accordingly, Lee fails to

disclose mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant as recited in claim 1.

2. Conclusion

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Accordingly, because claim 1 recites steps of mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant and Lee does not disclose any such method, the Applicants submit that the rejection of claim 1, as amended, is patentable over the prior art.

Discussion Regarding Patentability of Claims 4-5 and 8-10

Claims 4-5 and 8-10 depend, directly or by way of one or more intervening claims, from independent claim 1 and include the step discussed above with respect to claim 1 as well as other steps. Therefore, for at least the same reasons set forth above with respect claim 1, it is respectfully submitted that claims 4-5 and 8-10 are patentable over the prior art.

Discussion Regarding Patentability of Claim 13

1. Claim 13

Claim 13, as amended recites:

An implant for repair of a joint comprising:
a stem configured for implantation within a bone of the joint;
a head configured to replace a portion of the articulating aspect of the bone; and

a body operably connected to said head and said stem, said body including a surface defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the bone.

Thus, claim 13 recites an implant with a surface that defines a mechanical engagement feature, the feature being complementary to a feature formed in the removed bone tissue.

2. Lee Does Not Disclose an Implant Surface as Claimed

The Examiner rejected claim 13 based upon the proposition that Lee discloses an implant surface that defines a mechanical engagement feature. (Office Action at page 5). The Applicants respectfully traverse.

Specifically, the Examiner has alleged that the recited mechanical feature is disclosed by the slot 14 or member 20 of Lee. The member 20 is a bolt that is a component separate from the main prosthesis. Therefore, it is not possible for a surface of the main prosthesis to “define” the bolt. The surface may define a component compatible with the bolt, e.g., a slot. The bolt, however, cannot fairly be said to be a part of the surface.

The surface of Lee’s prosthesis does define a slot as noted above. The slot, however, is not complementary to a feature formed in the removed bone tissue. The slot only receives the bolt with an enlarged head and a second bolt to keep the first bolt within the slot. Thus, the slot is configured complementary to the head of a bolt, but not complementary to a surface feature of bone tissue. Lee does not disclose any bone tissue feature which informs the configuration of a surface feature of the prosthesis.

Therefore, Lee does not disclose a surface defining a mechanical engagement feature as claimed.

3. Caldarise Does Not disclose an Implant Surface as Claimed

Claim 13 was also rejected as being anticipated by Caldarise. (Office Action at page 5). Caldarise does not disclose an implant surface as recited in claim 13, as amended.

Specifically, the Examiner alleged that Caldarise disclosed a surface feature on a head of a prosthesis for engagement with a feature of a bone. (Office Action at page 5). Claim 13 has been amended to clarify that the surface which defines the surface feature is included on the body, not the head. Therefore, the Applicants believe that the rejection based upon Caldarise has been overcome.

Moreover, the recesses of Caldarise are located on the stem of an implant. (Caldarise at column 3, lines 62-67). Accordingly, they are wedged into a patient's femur and are therefore used with non-resected bone portions which have not been formed into a complementary feature. As shown in FIG. 2, there is a gap existent between the floor (f) of the recesses and the adjacent bone 50. This gap is limited to "below three millimeters" so as to allow bone from the "inner wall of the femur 50" to grow into the recess. (Caldarise at column 4, lines 46-54). Thus, the recesses of Caldarise are not configured based upon a surface feature of a resected bone portion.

4. Conclusion

Anticipation under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Accordingly, because claim 13 recites a “surface defining a mechanical engagement feature” that is complementary to a “feature formed in a removed portion of the bone” and Lee does not disclose any such surface of the prosthesis, and because Caldarise does not disclose a surface feature of a prosthesis that is used with a complementary shaped surface of a resected bone portion, the Applicants submit that claim 13, as amended, is patentable over the prior art.

Discussion Regarding Patentability of Claims 14-16

Claims 14-16 depend from independent claim 13 and include the element discussed above with respect to claim 13 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 13, it is respectfully submitted that claims 14-16 are patentable over the prior art.

V. The Rejection of Claims under 103(a)

Claims 7, 11, 12, 17 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of U.S. Patent No. 5,163,961 to Harwin (hereinafter “Harwin”) and/or U.S. Patent No. 4,889,110 to Galline et al. (hereinafter “Galline”) and claims 17 and 18 were further rejected under 35 U.S.C. 103(a) as being unpatentable over Caldarise in view of Harwin and/or Galline. The Applicants respectfully submit that in view of the foregoing amendments and the following remarks, claims 7, 11, 12, 17 and 18 are patentable over the prior art.

Discussion Regarding Patentability of Claims 7, 11 and 12

Claims 7, 11 and 12 were rejected based primarily upon Lee, with further reference to Harwin and/or Galline for teaching the additional anchoring means. (Office Action at page 6).

Claims 7, 11 and 12 depend, either directly or by way of intermediate claims, from claim 1 and thus include the step of mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant as was discussed above with respect to claim 1. Accordingly, because Lee does not teach, suggest or disclose the step of mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant, even modifying Lee to include the alleged anchoring means of Harwin or Galline does not arrive at the invention of claims 7, 11 or 12.

Therefore, because all of the limitations of claims 7, 11 and 12 have not been identified in the prior art as required by MPEP § 2143.03, the Examiner has failed to present a *prima facie* case of obviousness and the rejection of claims 7, 11 and 12 under 35 U.S.C. 103(a) should be withdrawn.

Discussion Regarding Patentability of Claims 17 and 18

Claims 17 and 18 were rejected based primarily upon Lee, with further reference to Harwin and/or Galline for teaching the additional anchoring means. (Office Action at pages 5- 6). Claims 17 and 18 were further rejected based primarily upon Caldarise, with

further reference to Harwin and/or Galline for teaching the additional anchoring means.
(Office Action at page 6).

Claims 17 and 18 depend from claim 13 and thus include the surface defining a mechanical engagement feature element as was discussed above with respect to the rejection of claim 13 over Lee. Thus, because Lee does not teach, suggest or disclose a mechanical engagement feature element, even modifying Lee to include the alleged anchoring means of Harwin or Galline does not arrive at the invention of claims 17 or 18.

Likewise, claims 17 and 18 include the surface defining a mechanical engagement feature element as was discussed above with respect to the rejection of claim 13 over Caldarise. Thus, because Caldarise does not teach, suggest or disclose a mechanical engagement feature element, even modifying Caldarise to include the alleged anchoring means of Harwin or Galline does not arrive at the invention of claims 17 or 18.

Therefore, because all of the limitations of claims 17 and 18 have not been identified in the prior art as required by MPEP § 2143.03, the Examiner has failed to present a *prima facie* case of obviousness and the rejection of claims 17 and 18 under 35 U.S.C. 103(a) should be withdrawn.

VI. Claims 19 and 20

Claims 19 and 20 have been added. These claims recite novel and non-obvious limitations. Accordingly, claims 19-20 are believed to be allowable over the prior art. Specifically, claim 19 recites the step of "mating the bone tissue feature with the feature of the implant while the natural soft tissue is still attached to the resected portion of bone." As discussed above, Lee discloses the mating of a bolt within a slot. Lee does not

disclose a bone tissue feature that mates with a feature of an implant. Therefore, claim 19 recites novel and non-obvious limitations with respect to Lee.

Additionally, claim 19 recites the step of “shaping the resected portion of bone to provide a bone tissue feature configured to mate with a feature of the implant.” As discussed above, the recesses of Caldarise are used with non-resected bone portions, not with a shaped resected bone portion. Therefore, claim 19 recites novel and non-obvious limitations with respect to Caldarise.

Claim 20 depends from claim 19 and include the elements discussed above with respect to claim 19 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 19, it is respectfully submitted that claim 20 is patentable over the prior art.

Moreover, the teaching of Harwin and Galline relied upon by the Examiner does not correct the deficiencies in the teaching of Lee and Caldarise. Therefore, it is respectfully submitted that claims 19 and 20 are not obvious over the prior art.

VII. Allowable Subject Matter

The Examiner has indicated that claims 2, 3 and 6 would be allowable if rewritten to include the limitations of the claims from which they depend. In view of the foregoing amendments and remarks, the Applicants believe that claims 2, 3 and 6 are in condition for allowance without further amendment.

VIII. Conclusion

Applicants respectfully request entry of the amendments and favorable consideration of the application.

A prompt and favorable action on the merits is requested.

Respectfully Submitted,
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